Department of Health and Human Services
Office of the Secretary

19-539

OFFICE OF MEDICARE HEARINGS AND APPEALS

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November 26, 2019

PARRISH LAW OFFICES
ATTN: DEBRA PARRISH
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PITTSBURGH, PA 15228

NOTICE OF DECISION

Appellant: A. PROSSER
OMHA Appeal Number: 3-8757160780

Enclosed is the decision for the above case. This decision is based on the administrative record, including any evidence or testimony presented at the hearing, if one was held. The decision is not precedential, does not release the appellant from civil or criminal liability, and may be reopened at any time if it was procured by fraud or similar fault. In addition, the decision may be reopened within 180 days of the decision for good cause. Good cause exists when there is new and material evidence that was not available or known at the time of the decision and may result in a different conclusion, or when the evidence that was considered clearly shows on its face that an obvious error was made at the time of the decision.

What if I disagree with the decision?

If you disagree with the decision, you may file an appeal with the Medicare Appeals Council. Other parties may also appeal the decision. In addition, the Medicare Appeals Council may decide to review the decision on its own motion. If no party appeals the decision and the Medicare Appeals Council does not review the decision, the decision is binding on all parties and you and the other parties will not have the right to ask a federal court to review the decision.

If you are not already represented, you may appoint an attorney or other person to represent you.

How much time do I have to file an appeal?

The Medicare Appeals Council must receive your written appeal **within 60 calendar days** of the date that you receive this notice. The Medicare Appeals Council assumes you received this notice 5 calendar days after the date of the notice unless you show that you did not receive it within the 5-day period.

The Medicare Appeals Council will dismiss a late request for review unless you show that you had a good reason for not filing it on time.

How do I file an appeal?

To appeal, you must ask the Medicare Appeals Council to review the decision. Your appeal must be in writing, except that a request for expedited review of a Part D decision may be made orally as described below. Your appeal must identify the parts of the decision that you disagree with, and explain why you disagree.

You may submit a written request for review to the Medicare Appeals Council using one of three available methods: mail, fax, or electronic filing (E-File). **Please do not submit your request for review using more than one method**. Regardless of how you file your appeal, **you must always send a copy of your written request for review to the other parties who received a copy of the decision.**

If you are filing a written request for review, you may use the enclosed *Request for Review* (Form DAB-101), or you may write a letter containing the following:

- The beneficiary's/enrollee's name (and telephone number for Part D appeals);
- The beneficiary's/enrollee's health insurance claim number;
- The item(s), service(s), or specific Part D drug(s) in dispute;
- The specific date(s) the item(s) or service(s) were provided, if applicable;
- For Part D appeals, the plan name;
- For Part D appeals, the OMHA Appeal Number on the adjudicator's dismissal;
- For Part D appeals requesting expedited review, a statement that you are requesting expedited review;
- The date of the adjudicator's decision (not required for Part D appeals); and
- Your name and signature, and, if applicable, the name and signature of your representative.

Filing by mail:

Mail your appeal and a copy of the enclosed decision to:

Department of Health and Human Services
Departmental Appeals Board
Medicare Appeals Council, MS 6127
Cohen Building Room G-644
330 Independence Ave., S.W.
Washington, D.C. 20201

Filing by fax:

Fax your appeal and a copy of the enclosed dismissal to **(202) 565-0227.**

Filing by computer:

Using your web browser, visit the Medicare Operations Division Electronic Filing System (MOD E-File) website at **https://dab.efile.hhs.gov/mod**.

To file a new appeal using MOD E-File, you will need to register by:

(1) Clicking **Register** on the MOD E-File home page;
(2) Entering the information requested on the "Register New Account" form; and
(3) Clicking **Register Account** at the bottom of the form.

You will use the email address and password you provided during registration to access MOD E-File at **https://dab.efile.hhs.gov/mod/users/new**. You will be able to use MOD E-File to file and access the specific materials for appeals to which you are a party or a party's representative. You may check the status of any appeal on the website homepage without registering.

Once registered, you may file your appeal by:

(1) Logging into MOD E-File;
(2) Clicking the **File New Appeal** menu button on the top right of the screen;
(3) Selecting the type of appeal you are filing (Request for Review or Request for Escalation); and
(4) Entering the requested Appeal Information and uploading the requested Appeal Documents on the "File New Appeal – Medicare Operations Division" form. You are required to provide information and documents marked with an asterisk.

At a minimum, the Medicare Appeals Council requires an appellant to file a signed Request for Review and a copy of the enclosed decision. All documents should be submitted in Portable Document Format (PDF) whenever possible. Any document, including a Request for Review, will be deemed to have been filed on a given day, if it is uploaded to MOD E-File on or before 11:59 p.m. EST of that day.

Currently, the documents that may be filed electronically are the:

(1) Request for Review;
(2) Appointment of Representative form (OMB Form 0938-0950);
(3) Copy of Administrative Law Judge or attorney adjudicator decision;
(4) Memorandum or brief or other written statement in support of your appeal; and
(5) Request to Withdraw your appeal

No other documents aside from the five (5) listed categories above may be submitted through MOD E-File.

Filing by oral request (for expedited review only):

Oral requests for expedited review of a Part D decision may be made by telephone to **(866) 365-8204.** You must provide the information listed in the bullet points above and a statement that you are requesting an expedited review. The Medicare Appeals Council will document the oral request in writing and maintain the documentation in the case file. Please note that your request for review will only be expedited if the Part D drug has not already been furnished and the prescribing physician (or other prescriber) indicates, or the Medicare Appeals Council determines, that the standard time frame may seriously jeopardize your life, health, or ability to regain maximum function.

How will the Medicare Appeals Council respond to my appeal?

The Medicare Appeals Council will limit its review to the issues raised in the appeal, unless the appeal is filed by an unrepresented beneficiary/enrollee. It may change the parts of the decision that you agree with. It may adopt, modify, or reverse the decision, in whole or in part, or it may send the case back to OMHA for further action. It may also dismiss your appeal.

Questions?

You may call or write our office. A toll-free phone number and mailing address are at the top of this notice.

Additional information about filing an appeal with the Medicare Appeals Council is available at http://www.hhs.gov/dab/. You can also call the Medicare Appeals Council's staff in the Medicare Operations Division of the Departmental Appeals Board at (202) 565-0100 or (866) 365-8204 (toll free), if you have questions about filing an appeal.

cc:

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Enclosures:

OMHA-152, Decision

OMHA-156, Exhibit List

Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Arlington, VA

Appeal of: **A. PROSSER**	OMHA Appeal No.: **3-8757160780**
Beneficiary: **A. PROSSER**	Medicare Part: B
Medicare No.: *******4857A**	Before: **Kenneth Bryant** Administrative Law Judge

DECISION

After considering the evidence and arguments presented in the record, the undersigned enters and **UNFAVORABLE** decision. The ("TTFT") (E0766) provided to the Appellant on February 16, 2019, and March 16, 2019, is not covered under the applicable LCD L34823 for these dates of service. The Supplier, Novocure, Inc., is responsible for the non-covered costs.

PROCEDURAL HISTORY

Novocure, Inc., the Supplier, submitted a claim to the Medicare Contractor ("Contractor") for tumor treatment field therapy ("TTFT") (E0766) provided to the Appellant on February 16, 2019, and March 16, 2019. The Contractor denied the claim initially and again upon redetermination. The Appellant then requested reconsideration from the Qualified Independent Contractor ("QIC"). On September 13, 2019, the QIC upheld the denial because the LCD L34823 clearly and unequivocally stated TTFT (E0766) would be denied as not reasonable and necessary. Based on the available documentation, the requirements of the LCD and PIM had not been met. Therefore, the claims could not receive reimbursement. The QIC held Novocure, Inc., the Supplier, liable for the non-covered costs. (File 3, pp. 1-15).

On October 4, 2019, the Office of Medicare Hearings and Appeals ("OMHA") received the Appellant's timely filed request for a hearing before an Administrative Law Judge ("ALJ"). (File 6, pp. 1-3). The amount in controversy meets the jurisdictional requirements for an ALJ appeal decision. 42 C.F.R. §405.1006. The record contains an Appointment of Representative form, which shows the Appellant appointed his attorney, Debra Parrish, Esq., as his representative. (File 6, p. 4). The hearing was originally scheduled for November 20, 2019, before Judge Kenneth Bryant. However, the hearing was rescheduled for November 22, 2019, as the Appellant's representative, Debra Parrish, Esq., advised she had not received the Notice of Hearing for the November 20, 2019, hearing. Ms. Parrish graciously consented to rescheduling the hearings for November 22, 2019. Ms. Parrish advised the Appellant would not be appearing at the hearing. Ms. Parrish argued and had no objections to the issues or evidence. Timothy Parks appeared as a witness in this appeal; he was sworn and testified. File 1, pages 44-67, File 2, pages 32-3231, and File 7, pages 67-101, 111-136, 138-262, consisting of medical literature and articles and ALJ decisions from other than the undersigned, were admitted as "reference material" only; there were no objections from the Appellant's representative. All of the remaining Files were admitted. (Hearing Record).

ISSUE(S)

1. Whether Medicare is required to provide coverage for tumor treatment field therapy (TTFT) (CPT E0766), pursuant to the statutory and regulatory provisions under Part B of Title XVIII of the Social Security Act (the "Act"), 42 C.F.R. §422 *et seq.*

APPLICABLE LAW AND POLICY

I. ALJ Review Authority

A. Jurisdiction

An individual who, or an organization that, is dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services (HHS), provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. (§ 1869(b)(1)(A) of the Act).

In implementing this statutory directive, the Secretary has delegated his authority to administer the nationwide hearings and appeals system for the Medicare program to OMHA. (See 70 Fed. Reg. 36386, 36387 (June 23, 2005). The ALJs within OMHA issue the final decisions of the Secretary, except for decisions reviewed by the Medicare Appeals Council. (Id.)

A hearing before an ALJ is only available if the remaining amount in controversy is one hundred thirty dollars ($130) or more. The request for hearing is timely if filed within sixty (60) days after receipt of a QIC reconsideration decision. (See 42 C.F.R. § 405.1014).

B. Scope of Review

Under the implementation policy of the Centers for Medicare and Medicaid Services, United States Department of Health and Human Services, all Medicare Part A and B claims, are governed by the Administrative Law Judge Hearing Procedures outlined in 20 C.F.R. §§ 404.929-404.961 and 42 C.F.R. § 405.855, or 42 C.F.R. . §§ 405.1000-405.1064. 70 Fed. Reg. 11424 (March 8, 2005).

The issues before the administrative law judge include all the issues brought out in the initial, reconsidered or revised determination that were not decided entirely in [the appellant's] favor. However, if evidence presented before or during the hearing causes the administrative law judge to question a fully favorable determination, he or she will notify [the appellant] and will consider it an issue at the hearing. 42 C.F.R. § 405.1032(a).

C. Standard of Review

The Office of Medicare Hearings and Appeals is staffed with Administrative Law Judges who conduct de novo hearings. 42 C.F.R. § 405.1000(d).

II. Principles of Law

A. The Social Security Act

The Supplementary Medical Insurance ("SMI") program, Part B of Title XVIII of the Social Security Act (the Act), entitles individuals who have enrolled in the program to have payment made to them or on their behalf, subject to certain provisions, for medical and other health services. Sections 1831 and 1832 of the Act *[42 U.S.C. §1395j and* 42 U.S.C. §1395k]. Individuals participate voluntarily in the Medicare Part B program and pay a monthly premium. Notwithstanding any other provision of Title XVIII of the Act, Section 1862(a) of the Act [42 U.S.C. §1395y(a)(1)(A)] limits the payments that may be made under Part A or Part B, stating in pertinent part that, "no payment may be made under Part A or Part B for any expenses incurred for items or services — (1)(A) which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member . . ." Id.; See also 42 C.F.R. §411.15(k)(1.) Additionally, Section 1833(e) of the Act [42 U.S.C. §1395l(e)] prohibits Medicare payment for any claim that lacks such information as may be necessary in order to determine the amounts due such provider.

Section 1879 of the Act states, in pertinent part: (a) Where – (1) a determination is made that, by reason of section 1862(a)(1) or (9) or by reason of a coverage denial described in subsection (g) [pertaining to certain home health services], payment may not be made under Part A or Part B of this title for any expenses incurred for items or services furnished by an individual by a provider of services or by another person pursuant to an assignment under section 1842(b)(3)(B)(ii), and (2) both such individual and such provider of services or other such person, as the case may be, did not know, and could not reasonably have been expected to know, that payment would not be made for such items or services under such Part A or Part B, then to the extent permitted by this title, payment shall, notwithstanding such determination, be made for such items or services (and for such period of time as the Secretary finds will carry out the objectives of this title), as though section 1862(a)(1) and section 1862(a)(9) did not apply and as though the coverage denial described in subsection (g) had not occurred. *42 U.S.C. § 1395pp.*

Section 1871(a)(2) of the Act provides that no rule, requirement or statement of policy, other than a NCD, can establish or change a substantive legal standard governing the scope of benefits or payment for services under the Medicare program unless it is promulgated as a regulation by CMS. However, although not subject to the force and effect of the law, CMS and its contractors, have issued policy and guidelines that describe criteria for coverage for selected types of medical services and supplies. No NCD has been issued for these services.

B. Policy and Guidance

The Secretary of HHS requires Medicare contractors to develop and use LCDs to aid in the evaluation of whether a particular service, procedure or item is reasonable and necessary for the treatment of a Beneficiary's condition, specifically, when the contractor identifies an item or service that is never covered in certain circumstances and wishes to establish automated review or when widespread, significant risk to Medicare funds dictates. (Medicare Program Integrity Manual (MPIM) Ch.13 § 4.B). The term "LCD" is a creation of the Benefits Improvement and Protection Act of 1997. (MPIM, Ch. 13 §1.3; *See also*, §1869 of the Act). Prior to this new terminology, carriers issued LMRPs that served the same purpose and carry the same weight as LCDs. (*Id.*). LCDs and LMRPs are used only on a contractor-wide basis and may differ between contractors in different regions of the country. (§1869(f)(2)(B)). LCDs and LMRPs are binding upon carriers making initial coverage eligibility determinations, but are not binding upon ALJs.

(§1869(f)(2)(A)(i)). CMS Medicare Coverage Database, Local Coverage Determination L34823: Tumor Treatment Field Therapy ("TTFT") (LCD L34823) (eff. Jan. 1, 2017 – Aug. 31, 2019) applies in this case.

FINDINGS OF FACT AND ANALYSIS

1. On March 15, 2018, the Beneficiary, a 35-year-old female during the dates of service at issue, visited the neuro-oncology clinic for further evaluation and management of a left temporal Grade 4 astrocytoma. (File 1, pp. 17-20). Since her last visit, she had remained on TTFields with 91% compliance for March. (*Id.* at 17). She was using clobetasol as needed and they rotated around open lesions. *Id.* She was doing great neurologically with no other symptoms and was otherwise healthy. *Id.* On February 14, 2016, a MRI revealed a large left cystic temporal mass. *Id.* On February 25, 2016, she underwent a left craniotomy – GBM. *Id.* In May 2016 she completed radiation with concurrent temodar. *Id.* In June 2016 she continued with adjuvant temodar. *Id.* On June 16, 2016, she started Optune TTFields. *Id.* In April 2017 she completed 12 cycles of temodar and continued TTFields. *Id.* Her past medical history included Crohn's disease and Wolff-Parkinson-White syndrome. *Id.* An MRI, done on March 15, 2018, showed she was radiographically stable. (*Id.* at 20). She was neurologically intact. *Id.* She was tolerating TTFields well and had excellent compliance. *Id.* Recommendations included for GMB, continuing Optune TTFields and Clobetasol for skin irritation; and RTC for three months with a MRI. *Id.*

2. On April 13, 2018, and October 11, 2018, the physician ordered renewal prescriptions for Optune. (File 7, pp. 32-33). The diagnosis was glioblastoma multiforme (C71.9). *Id.* The period was for six months. *Id.*

3. The Beneficiary visited the neuro-oncology clinic on December 19, 2018, for further evaluation and management of a left temporal Grade 4 astrocytoma. (File 1, pp. 21-25). Since her last visit, she had remained on TTFields with 92% compliance in November. (*Id.* at 21). A December 19, 2018, MRI of the brain showed a stable brain MRI compared to one taken on September 18, 2018. (*Id.* at 24). There was no evidence of disease progression. *Id.* There was no focal hyperperfusion to suggest tumor angiogenesis. *Id.* The physician's assessment was the MRI showed no active disease and the tumor was smaller compared to a MRI done two years ago. *Id.* This was likely due to her previous treatment with radiation and TM2 and her ongoing treatment with TTFields. *Id.* She continued to tolerate TTFields with no significant side effects. *Id.* Recommendations included for GMB, continuing Optune TTFields and Clobetasol for skin irritation; and RTC for three months with a MRI. *Id.*

4. On March 11, 2019, the Beneficiary underwent a MRI of the head. (File 1, p. 38). The findings were suspicious for residual or recurrent neoplasm in the left temporal lobe posterior to the resection cavity. *Id.*

5. Ms. Parrish, the Appellant's representative, argued, in relevant part: The Appellant is a 36 year old female (mother, spouse) who in February 2016 was newly diagnosed with a glioblastoma (GBM) after experiencing intractable migraines. The Appellant had surgery and chemo-radiation; completing chemo-radiation in May 2016. The Appellant was prescribed the Optune system to treat her GBM and began using in June 2016 with adjuvant temozolomide. The operative LCD, as applied to this case, is invalid; a

challenge to reconsider was made in June 2018; should have been completed by September 2018; contractor failed to meet the deadline; as such the order was invalid as applied to the dates of service in this appeal which post-date September 2018. The LCD was subsequently revised, effective coverage date starting in September 2019, such revision after a challenge had been filed is further reason the LCD is invalid. The evidence and literature is compelling the Optune system was keeping this Appellant alive. LCDs are not binding on ALJs; ALJs are to review *de nova*; there are multiple Federal Register citations supporting the non-binding nature of an LCD; in this case the undersigned should not follow the invalid LCD. Additionally, this Appellant has received multiple FAVORABLE decisions from other ALJs. As such, collateral estopple applies to all and this appeal also be deemed FAVOABLE. This Appellant would have satisfied the criteria of the recently released LCD had the LCD been timely revised. (Hearing Record).

6. Mr. Parks, witness, testified in relevant part: As noted, the Appellant is a 36 year old female (mother, spouse) who in February 2016 was newly diagnosed with a glioblastoma (GBM) after experiencing intractable migraines. MRI in February confirmed a mass; mass surgically removed 2/25/16, GBM confirmed. Completed chemo-radiation in May 2016; was prescribed the Optune system to treat her GBM; began using in June 2016 with adjuvant temozolomide. Subsequent MRIs in 2017 were stable, no progression noted. Completed chemo-therapy in April 2017; continued on Optune system. Since then, MRIs from March 2018 up through March 2019 shown no progression/stable. Appellant has 78% compliance rate; and a 80 score. (Hearing Record).

Analysis

Novocure, Inc., the Supplier, is asking Medicare to provide coverage of tumor treatment field therapy ("TTFT") (E0766) provided to the Beneficiary on February 16, 2019, and March 16, 2019. The QIC upheld the denial because the LCD L34823 clearly and unequivocally stated TTFT (E0766) would be denied as not reasonable and necessary. Based on the available documentation, the requirements of the LCD and PIM had not been met. Therefore, the claims could not receive reimbursement. The QIC held Novocure, Inc., the Supplier, liable for the non-covered costs. (File 3, pp. 1-15).

First, the undersigned understands the Medicare Contractors have issued a revised LCD L34823 and Policy Article A52711 for Medicare beneficiaries with newly diagnosed glioblastoma with an effective date of September 1, 2019. As stated in the new LCD's Revision History Information, the dates of service of the previous LCD, in which TTFT was deemed not coverable, are before this effective date; specifically, the dates of service span from February 16, 2019, and March 16, 2019. Therefore, the previous LCD L34823 applies to this case. Although the new LCD has revised the LCD provision in regards to coverage for TTFT, it has not completely removed the old provision for TTFT coverage because it specifies the old provision applies to services performed before September 1, 2019.

Next, Ms. Parrish argued LCD L34823 is not valid because a revision of an LCD after a challenge has been filed has the same effect as a judicial ruling the LCD was invalid. (Hearing Record; Files 6 and 9). Ms. Parrish cited 42 C.F.R. § 426.420(b) which states "a contractor may revise an LCD under review to remove or amend the LCD provision listed in the complaint through the reconsideration process before the date the ALJ issues a decision regarding that LCD. Revising an LCD under review to remove the LCD provision in question has the same

effect as a decision under § 426.460(b)." However, the cited provisions are unspecific with respect to when the LCD becomes invalid; nothing in this and the associated regulation leads the undersigned to the conclusion the LCD is invalid retroactively. To follow this argument, is to try to determine an effective date other than the one listed on the revised LCD at some indefinite point in the past. The undersigned does not have jurisdiction to do this of his own accord, and declines to follow this line of argument. In addition, even assuming arguendo the undersigned agreed with Appellant's position the LCD is invalid, the cited provision does not provide any direction for the undersigned to pursue. Instead, though the LCD might be considered "invalid", 42 C.F.R. § 426.460(b) only provides the methods the lower levels must pursue to re-open and re-adjudicate the case.

After reviewing the record and the Appellant's contentions, the undersigned concludes the TTFT (E0766) provided to the Appellant on February 16, 2019, and March 16, 2019, is not covered by Medicare. In this case, the record demonstrates the Appellant was diagnosed with left frontal gliosarcoma. (File 1; File 7). For this condition, she has been receiving Optune TTFT treatment. *Id.* Under the applicable LCD L34823, "tumor treatment field therapy (CPT E0766) will be denied as not reasonable and necessary." In addition, Policy Article A52711 states:

> Tumor treatment field therapy devices are covered under the Durable Medical Equipment benefit (Social Security Act §1861(s)(6)). In order for a beneficiary's equipment to be eligible for reimbursement the reasonable and necessary (R&N) requirements set out in the related Local Coverage Determination must be met.

To be covered under Medicare, treatment and devices must be both reasonable and necessary for the prevention of illness or for the diagnosis and treatment of illness or injury. Because TTFT is categorized by the LCD as not reasonable and necessary, payment for it cannot be made under the durable medical equipment benefit under Section 1861(n) of the Social Security Act (Act). See Policy Article A52711.

Although not bound by LCDs, Medicare regulations require ALJs and the Medicare Appeals Council (hereafter, "Council") to "give substantial deference to these policies if they are applicable to a particular case." 42 C.F.R. §405.1062(a). The Appellant's representative, Debra Parrish, Esq., has argued the QIC did not consider any of the medical literature, tests, reviews which existed at the time of their decision. (File 6, pp. 1-3; File 9, pp. 3-4). Medicare should provide coverage for TTFT treatment, which is a widely accepted treatment. *Id.* Ms. Parrish argued the procedure was medically reasonable and necessary, and should be approved. *Id.*

However, the applicable LCD for these dates of service-LCD L34823-states Optune is not covered by Medicare. The LCD is quite specific and covers dates of service from January 1, 2017, to August, 31, 2019. According to the Medicare Appeals Council, in an unpublished decision, and thus non-binding, "the Medicare Program Integrity Manual ("MPIM") sets forth the purpose, development, and use of LCDs in the context of determining Medicare coverage." *In re J.G., No. M-19-525 (Medicare Appeals Council Mar. 14, 2019)* (citing CMS, *Medicare Program Integrity Manual (MPIM) (Internet-Only Manual Publ'n 100-08)* ch. 13). The Council also stated in the same decision "the MPIM states, 'LCDs specify under what clinical circumstances an item or service is considered to be reasonable and necessary. They are administrative and educational tools to assist providers in submitting correct claims for payment. Contractors publish LCDs to provide guidance to the public and medical community within their jurisdictions. Contractors develop LCDs by considering medical literature, the advice of local medical societies and medical consultants, public comments, and comments from the provider

community.' *Id.*, (citing *MPIM*, ch. 13, § 13.1.3). The undersigned adopts for this decision the language used by the Council in the aforementioned decision.

Nevertheless and therefore, the undersigned will not decline to defer to the applicable LCD based on an argument it is not supported by the medical community or medical research. As stated by the Council in the previously noted decision, "in developing LCDs, contractors consider medical literature and research, and LCDs are reviewed annual to ensure all LCDs remain accurate and up-to-date at all times." *Id.*, (citing *MPIM*, ch. 13, §13.4). The undersigned again adopts for this decision the language used by the Council in the aforementioned decision.

The undersigned has, of course, reviewed and considered the reference material provided by the Appellant, specifically, Files 1, 2 and 7. The undersigned specifically reviewed the FAVORABLE redacted decisions by other ALJs regarding similar issues as presented with this Beneficiary. (File 1, pp. 44-67; File 2, pp. 1643-3231). The record includes a Civil Remedies decision, which did not distinguish between recurrent and newly diagnosed in evaluating the LCD and concluded the record upon which the LCD was based was insufficient to support the LCD. *See In re LCD Complaint: Tumor Treatment Field Therapy*, No. C-19-396 (Departmental Appeals Board, Civil Remedies Division May 28, 2019) (File 2, pp. 32-36).

The undersigned is limited to the applicable statutes, regulations, CMS rulings, precedential Medicare Appeals Council decisions, and National Coverage Determinations in making a decision. See 42 C.F.R. §§ 401.108, 405.1060, 405.1062, 405.1063. Also, the undersigned must give substantial deference to Local Coverage Determinations and CMS program guidance unless there is a reason particular to a specific case that supports deviation from the Contractor's judgment. *Id.* The undersigned is not bound by decisions issued by the Civil Remedies Division of the Departmental Appeals Board.

Appellants' representative further argued at hearing the delay in issuing the revised LCD unfairly affected this Beneficiary. (Hearing Record). While that may be an unfortunate truth, the undersigned does not have jurisdiction to make a determination as to the fairness of the LCD revision process or the length thereof.

Additionally, Appellants' representative notes in her brief the Beneficiary's tumor treatment field therapy should be covered because it was covered before. She asserts the doctrines of collateral estoppel and issue preclusion prevent finding otherwise citing to a Supreme Court decision, *Astoria Federal Savings and Loan Assoc. v. Solimino*, 501 U.S. 104 (1991). In this case, the Supreme Court speaks of applying these doctrines to "determinations of administrative bodies that have attained finality". This appeal concerns dates of service January 13, 2019, February 13, 2019, and March 13, 2019. These dates of service represent new matters on which there has been no determination attaining finality. Collateral estoppel only applies if the disputed issue is the same as the issue determined in the original action. (*Blonder-Tongue Laboratories, Inc. v. University of Ill. Found.*, 402 U.S. 313, 323 (quoting *Bernhard v. Bank of Am. Nat'l Trust & Say. Ass'n*, 19 Cal.2d 807, 813, 122 P.2d 892, 895 (1942)). This requirement in the administrative context is further discussed in *Hercules Carriers, Inc. v. Claimant State of Florida*, 768 F.2d 1558, 1578 n.13 (11 th Cir. 1985), which notes one prerequisite to application of collateral estoppel is "that the issue at stake be identical to the one involved in the prior litigation". *Lightsey v. Harding, Dahm & Co.*, 623 F.2d 1219, 1221 (7th Cir. 1980), further states, "for collateral estoppel effect to be given to an order of an administrative agency, the court must find that the same disputed issues of fact were before it as are before the court." The issue at stake here is not identical to previously adjudicated in Appellants' favor, accordingly, though the

undersigned acknowledges the representative's argument, the undersigned declines to cede to this position.

The undersigned is very sympathetic to the Appellant's position, the seriousness of the diagnosis, and the lack of remaining options. Additionally, the judgment of the Appellant's physicians and potential benefit of the treatment is not at issue, although it appears the physicians may not have been clear with regard to potential coverage issues for TTFT. However, 42 C.F.R. §405.1062 requires substantial deference be given to the applicable LCD unless there is a reason particular to a specific case that supports deviation from the Contractor's judgment. Moreover, the Council has, in another unpublished decision, which the undersigned herein adopts, made clear cases involving coverage determinations are not the proper forum for inquiries into the reasonableness of an LCD. *In re BlueCross BlueShield of North Carolina, No. M-15-1354* (Medicare Appeals Council Jan. 2016).

Based on the foregoing considerations, the Appellant's claim for tumor treatment field therapy ("TTFT") (E0766) provided to the Appellant on February 16, 2019, and March 16, 2019, is not sufficiently documented to satisfy the requirements for coverage pursuant to the applicable Medicare coverage criteria. (*See also* § 1833(e) of the Act, 42 C.F.R. § 424.5(a)(6), LCD L34823). Accordingly, the item was not medically reasonable and necessary pursuant to § 1862(a)(1)(A) of the Act.

Limitation on Liability

The file did not contain an ABN or any other form of notice. The Beneficiary neither knew, nor reasonably should have been expected to know, that any of the services would not be covered by Medicare. The liability of the Beneficiary is waived. The Supplier either knew, or reasonably should have been expected to know, that the services denied would not be covered by Medicare. The Supplier is presumed to have knowledge of published Medicare coverage rules, regulations, and guidelines. As a result, the Supplier is not eligible for a waiver of liability, pursuant to § 1879 of the Act, and is liable for the non-covered charges.

CONCLUSIONS OF LAW

The tumor treatment field therapy ("TTFT") (E0766) provided to the Appellant on February 16, 2019, and March 16, 2019, was not medically reasonable and necessary, as required by Section 1862(a)(1)(A) and Section 1833(e) of the Act. Therefore, payment may not be made under Part B. Pursuant to Section 1879 of the Act, the Supplier is liable for the non-covered charges.

ORDER

For the reasons discussed above, this decision is **UNFAVORABLE**. The Supplier, Novocure, Inc., is responsible for the non-covered costs. The undersigned directs the Medicare administrative contractor/to process the claim in accordance with this decision.

SO ORDERED

Kenneth Bryant
Administrative Law Judge

Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Arlington, VA

Appeal of: **A. PROSSER**	OMHA Appeal No.: **3-8757160780**
Beneficiary: **A. PROSSER**	Medicare Part: **B**
Medicare No.: *******4857A**	Before: **Kenneth Bryant** Administrative Law Judge

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